

REMARKS

Status of the Claims

Claims 1-4 and 10-25 are pending.

Restriction

Restriction between one of three allegedly distinct groups has been required:

Group I (claims 1-4 and 15-25), drawn immunogenic detoxified LT or CT proteins;

Group II (claims 10-11) drawn to methods of vaccinating to prevent or treat disease in a subject using the immunogenic detoxified proteins of Group I; and

Group III (claims 12-14), drawn to methods of formulating a vaccine.

Applicants elect Group I, with traverse.

Applicants traverse on the grounds that it would not be unduly burdensome to search all the Groups together. Indeed, because all claims depend from claim 1, a search of the art for detoxified proteins having the recited amino acid substitutions would necessarily and inevitably reveal references relevant to methods of using and making these particular proteins. Since one such search would reveal all relevant references, searching the claims of Groups I, II and III together would not be unduly burdensome and would in fact save time and resources.

In any event, the method claims of Groups II and III contain all the limitations of elected Group I. Therefore, rejoinder of Groups II and III is in order.

Election of Species

The Examiner, in the Election Requirement, required election of one species in each of the following groups if Group I was elected:

- 1) cholera toxin subunit A with a mutation through substitution of Asn or Gly;
- 2) cholera toxin subunit A with a mutation through substitution of Asn or Gly;
- 3) *E. coli* heat labile toxin subunit A with a mutation through substitution of Asn or Gly;
- 4) cholera toxin subunit A with cholera toxin subunit B;
- 5) cholera toxin subunit A with cholera toxin subunit B; and
- 6) *E. coli* heat labile toxin subunit A with subunit B.

As a threshold matter, Applicants first note that the claims are not drawn to mutations in Asn or Gly, but to substitutions at positions Ser-63 and Arg-192 of SEQ ID NO:7 or SEQ ID NO:8. (See, claim 1 as set forth in Second Preliminary Amendment filed December 15, 2003). Thus, clarification is requested.

Furthermore, Applicants also request clarification as to the difference between species 1 and 2 and species 4 and 5. In particular, species 1 and 2 are both drawn to cholera toxin subunit A having mutations (substitutions) in Asn or Gly and the Examiner indicates both read on claims 15-18 and 23. Similarly, species 4 and 5 are both drawn to “cholera toxin A subunit with cholera toxin subunit B (claims 4 and 23-24).” Therefore, species 1 and 2 as well as species 4 and 5 appear to be duplicative of each other.

In any event, Applicants **traverse** the election of species requirement on the grounds that a search for each allegedly distinct species is in no way unduly burdensome. Indeed, a search of the art for any mutant of SEQ ID NO:7 at positions 63 and 192 would necessarily and inevitably reveal art relevant to a mutant of SEQ ID NO:8 (which also has a Ser at position 63 and an Arg at position 192), including references relevant to these mutant proteins in combination with other proteins (*e.g.*, subunit B). There is no search burden involved in searching all species together and accordingly, the election of species requirement should be withdrawn.

Solely to be fully responsive, Applicants elect, with traverse: Species (3)

E. coli heat labile toxin subunit A where positions Ser-63 is replaced with Lys-63 and Arg-192 is replaced with another amino acid, which reads on claims 1-4, 10-14, 19-23 and 25.

It is to be understood that the foregoing election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species. *See*, M.P.E.P. § 809.

Conclusion

Applicants expressly reserve their right under 35 USC § 121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.


Furthermore, should the Examiner choose to make this restriction requirement FINAL, Applicants reserve their right, pursuant to 37 C.F.R. §§ 1.144 and 1.181, to petition this requirement at any time during the pendency of this application, prior to appeal.

Please direct all further written communications regarding this application to:

Alisa Harbin
NOVARTIS VACCINES AND DIAGNOSTICS
Intellectual Property - R440
P. O. Box 8097
Emeryville, CA 94662-8097

Respectfully submitted,

Date: March 21, 2007

By: 
Dahna S. Pasternak
Registration No. 41,411
Attorney for Applicants

NOVARTIS VACCINES AND DIAGNOSTICS, INC.
Intellectual Property - R440
P. O. Box 8097
Emeryville, CA 94662-8097
Tel.: (650) 493-3400; Fax: (650) 493-3440